

MAY 09 2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
Group Art Unit 1634

In re

Patent Application of

Rex M. Bitner, et. al.

Serial No. 09/711,782

Filed: November 13, 2000

Examiner: Bradley L. Sisson

"LYSATE CLEARANCE AND NUCLEIC ACID  
ISOLATION USING SILANIZED SILICA  
MATRICES"

I, Diane J. Frauchiger, hereby certify that this correspondence is being deposited with the US Postal Service as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231, on the date of my signature

*Diane J. Frauchiger*  
Signature  
*April 29, 2002*  
Date of Signature

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RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

In response to an Office Action mailed March 27, 2002 (Paper No. 6), the one month period for responding to the restriction requirement falls on April 27, 2002. Because April 27, 2002 was a Saturday, this Response is timely filed on April 29, 2002. No fee is believed due in connection with this response. However, if a fee is owed, please charge such fee to deposit account number 50-0842.

Claims 1-51 are pending in the application. The Examiner asserted that "[C]laims 1-48 are generic to a plurality of disclosed patentably distinct species comprising the various molecular species encompassed by each of R<sub>1</sub>, R<sub>2</sub>, and R<sub>3</sub>." (See page 2, ¶1 of the Office Action). In addition, the Examiner required that Applicants elect a single disclosed species for each of R<sub>1</sub>, R<sub>2</sub>, and R<sub>3</sub>. Applicants respectfully traverse the restriction requirement for the reasons set forth below.

A proper requirement for restriction requires: (1) the inventions must be independent or distinct as claimed; and (2) there must be a serious burden on the Examiner if restriction is not imposed.

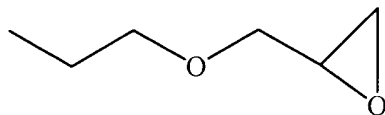
Applicants submit that restriction is not appropriate in this case because examining the claims together would not impose a serious burden on the Patent Office. The MPEP provides that "If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." (MPEP 803). Specifically, MPEP 803.02 provides that "if the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits...."

Furthermore, section 803.02 of the MPEP, cites caselaw, standing for the proposition that "it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. (See *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978)). "Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility." (See *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).)

Applicants submit that the species for each of  $R_1$ ,  $R_2$ , and  $R_3$  are not patently distinct and are in fact obvious variants of each other. The species of  $R_1$ ,  $R_2$ , and  $R_3$  are related in that they all facilitate hydrogen bonding networks that exist in water that make the target molecules, i.e., nucleic acids and proteins thermodynamically stable. The species of  $R_1$ ,  $R_2$ , and  $R_3$  are also related in that they are ion-exchange ligands which can be covalently attached to silica magnetic particles, and have the capacity to exchange with the target molecule (i.e., can act as cation exchangers at one pH and as an anion exchanger at another pH). Such magnetic particles are particularly well suited for use in the methods of the present invention, because substrates can selectively adsorb to the hydrous siliceous oxide adsorptive surface of the particle through hydrophobic interactions, to the ion exchange ligands through ion exchange, or to both the surface and ion exchange ligands, depending upon solution conditions. (See page 8 of the Specification, lines 20-27).

The species for each of  $R_1$ ,  $R_2$ , and  $R_3$  are so inextricably related to one another that, for the sake of efficiency, all of the species for each of  $R_1$ ,  $R_2$ , and  $R_3$  should be examined in a single application. A complete search of the prior art relating to this common feature would

necessarily require a search of the subject matter for each of R<sub>1</sub>, R<sub>2</sub>, and R<sub>3</sub>. Given the close relationship between the species for each of R<sub>1</sub>, R<sub>2</sub>, and R<sub>3</sub>, prosecution in the same application would be administratively efficient for the Patent Office. Nevertheless, Applicants elect, with traverse, the hydroxy group as the disclosed species for R<sub>1</sub> and R<sub>2</sub>. Applicants, also elect, with traverse, the epoxy of general formula III (See pg. 19, line 18) and herein below:



for R<sub>3</sub>. Applicants respectfully request that the requirement to elect between the disclosed species for each of R<sub>1</sub>, R<sub>2</sub>, and R<sub>3</sub> be withdrawn.

Furthermore, the present application does not recite such a multiplicity of species that an unduly extensive and burdensome search is required. Nevertheless, Applicants elect the hydroxy group for R<sub>1</sub> and R<sub>2</sub>, and the epoxy of general formula III (See pg. 19, line 18) for R<sub>3</sub>, with traverse. Applicants respectfully request that the requirement to elect a species be withdrawn.

Applicants invite the Examiner to contact the undersigned should further clarification concerning this response be required.

Respectfully submitted,

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